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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/488,164	06/07/1995	JOHN J. KOPCHICK	7707-015	8450
1444	7590	12/15/2003		
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER SAOUD, CHRISTINE J	
			ART UNIT 1647	PAPER NUMBER

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 08/488,164	<b>Applicant(s)</b> KOPCHICK ET AL.	
	<b>Examiner</b> Christine J. Saoud	<b>Art Unit</b> 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32,38,40-43,107,109,110 and 120-162 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32,38,40-43,107,109,110,120-138,140-158,161 and 162 is/are allowed.
- 6) ☒ Claim(s) 159 and 160 is/are rejected.
- 7) ☒ Claim(s) 139 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's amendment filed 15 August 2003 has been received and entered. The status of the claims is as follows: Claims 1-31, 33-37, 39, 44-106, 108, 111-119 are canceled and claims 32, 38, 150, and 162 have been amended as requested. Claims 32, 38, 40-43, 107, 109-110, 120-162 are pending and under consideration in the instant Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments and amendments filed in the response of August 15, 2003 have been fully considered, but they are not fully persuasive for the reasons that follow.

### ***Claim Objections***

Claim 139 remains objected to because of the following informalities: in the second to last line of the claim, there is a comma between "yellowtail" and "tuna", however, a fair reading of the art would suggest that "yellowtail" is used to describe a type of tuna for which the amino acid sequence of growth hormone from this species is

described (see Watahiki (1988)). Therefore, the comma which appears between the terms “yellowtail” and “tuna” should be deleted. Appropriate correction is required.

It is additionally noted that this error also occurs at page 17, line 21 of the specification. If Applicant has evidence that “yellowtail” and “tuna” are used in the art to describe two different species of fish and their corresponding species of growth hormone were known in the art at the time of the instant invention, this objection will be withdrawn.

Applicant's comments regarding the use of the plural “growth hormones” in claim 139 is noted. However, for clarification, the use of the term “growth hormone” is being interpreted as those molecules which correspond to and are species homologs of the growth hormone in bovine and humans with the known amino acid sequences described in the instant specification. Therefore, species variants which could be deletion variants, allelic variants, truncation variants, etc. are what would be considered “growth hormones”. The use of the term “growth hormones” in the claim is not interpreted as any member of the growth hormone superfamily, and therefore would not encompass prolactin, placental lactogen, etc. If Applicant disagrees with this interpretation, the instant claim could be subject to a new ground of rejection.

### ***Claim Rejections - 35 USC § 112***

Claims 159-160 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record.

Claims 159 and 160 recite “at least as large in volume as proline” and “ at least as large in volume as leucine”, which renders the claims unclear and indefinite for the reasons of record. Applicant indicates a willingness to replace the present limitations with a list of amino acids that are intended by the current limitations. Amendment of the claims to recite a list of the amino acids which are to be substituted would obviate this ground of rejection.

***Allowable Subject Matter***

Claims 40-43, 107, 109-110, 120-138, 140-158, 161-162 are allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 703-305-7519. The examiner can normally be reached on Monday through Thursday, 8AM to 2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*